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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,896	09/25/2003	JoAnn Hotta	B185 1180.1 (MSC 8011)	5988

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,896	HOTTA ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *8-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/17/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-7, 26 and 27, in the reply filed on March 17, 2006 is acknowledged.

The requirement is still deemed proper and made FINAL.

Claims 8-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 17, 2006.

Claims 1-7, 26 and 27 and linking claims **24 and 25** have been examined on the merits.

Information Disclosure Statement

Applicant's IDS submission of May17, 2004 has been considered. References not in English have been considered to the extent of the provided statement of relevance and/or English abstract.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 recite, "the solution containing immunoglobulin is", and it is unclear whether it is the starting solution or the resulting nanofiltered solution that is of the recited purities, particularly since the claims are drafted to be methods of purification.

Claims 1, 7, 24, 26 and 27 recite, "normal flow conditions," which is vague and indefinite, as 'normal' is a relative term, subject to interpretation of the observer, and is not defined in the specification in such a way that one would know what rate of flow is 'normal'.

Claims 1, 26 and 27 recite, "sufficiently pure," which is vague and indefinite, as 'sufficiently' is a relative term, subject to interpretation of the observer, and is not defined in the specification in such a way that one would know what degree of purity is 'sufficiently pure'.

Claims 26 and 27 recite methods of nanofiltration of immunoglobulin preparations and within the claim it further recites, "wherein the solution containing immunoglobulins is prepared from a starting solution...," followed by several methods steps, and it is unclear whether the 'wherein' phrase is required to practice the instant nanofiltration method, as it defines a product by process. The product collected in the delineated steps (d) and (e) in claims 26 and 27, respectively, does not result in a solution of immunoglobulins, as required for practicing the nanofiltration method, but rather a separate product 'collected immunoglobulin'.

Claim 27 recites, "by performing the sequential steps a) through e)..., the method further comprising the non-sequential step of f)... separating the precipitate from the supernatant solution after at least one of steps b) or c)," (emphasis added), which is unclear and indefinite, as it is unclear how one could practice sequential steps and practice a non-sequential step within those same steps. If one were to practice the method, a)-b)-f)-c)-d)-e), one is no longer practicing the steps sequentially, and thus the claim is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 24-27 are rejected under 35 U.S.C. 102(a) as being anticipated by HOTTA (J. Hotta, et al.; D6: PTO-1449, 5/17/04).

The instant claims are drawn generally to nanofiltration of immunoglobulin (Ig).

Hotta teaches nanofiltration of Ig through 1 or 2 filters of 20 nm pore size (20N) at pH 4 or 5 resulting in at least 97% recovery of Ig at a flow rate of ≤ 12 psi filtering PPV as the model for HPV B19. Please note, the broadest reasonable interpretation of about 35 nm includes 20N filters. Additionally, in this interpretation the method of obtaining the starting material ('wherein...') does not confer patentable weight to the method of nanofiltration of Ig.

Claims 1-7 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by VAN HOLTEN (US Patent 6,096,872; P3: PTO-1449, 5/17/04).

The instant claims are presented *supra*.

Van Holten teaches a method of making a substantially pure, virus free Ig comprising nanofiltration using a filter that is less than about 30 nm pore size (e.g. claims 1 and 28) and 12 nm (claim 2). Van Holten further teaches a second filtration (e.g. claim 23). The filtration is considered to be under constant flow, as in Comparative Example 2A, e.g.,, the ultrafiltration system was run at 15 ml/min for 28 minutes.

Because one is using an isolated Ig fraction in the purification, one would necessarily obtain 'about 99% pure' Ig. Please note, the broadest reasonable interpretation of 'about 15'

includes 12 nm as well as the 10-60 KDa filtration (approximately 5 nm pores) and 'about 25' includes 'less than about 30'. Additionally, in this interpretation the method of obtaining the starting material ('wherein...') does not confer patentable weight to the method of nanofiltration of Ig. Further, in practicing the method of Van Holten, one would inherently be reducing any and all viral contaminants, including HPV B19 and Hepatis A virus, as one is practicing the same method steps as instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over VAN HOLTEN as applied to claims 1-3, 7 and 24-27 above, and further in view of LEBING (US Patent 5,886,154; P4: PTO-1449, 5/17/04).

Please note, the rejection is set forth for claims 26 and 27 under the interpretation that the method of obtaining the Ig is a claim limitation.

The instant claims are presented *supra*. The teachings of Van Holten are presented *supra*.

Lebing teaches the recited steps of instant claim 27 for obtaining Ig with inactivated viruses (claim 1) and that the method results in greater than 99% purity (column 3, lines 10-13).

The difference between the prior art, and that which is instantly claimed is that the prior art does not teach double filtration, and Lebing does not teach using nanofiltration to separate the Ig preparation.

It would have been obvious at the time of the invention to have used the method of Van Holten to separate the purified Ig of Lebing from the inactivated viruses, in order to make a sterile, ultrapurified Ig.

One would have been motivated to use the method of Van Holten to ultrapurify and sterilize the Ig of Lebing, as nanofiltration is required to remove small viruses from Ig (e.g. Van Holten, column 1, lines 17+) and Holten teaches the method is effective for making virus free preparations of Ig.

One would have had a reasonable expectation for success in combining the two methods, as Lebing teaches the method of making purified requires separation of the Ig from non-enveloped viruses (claim 1, f) and that double ultrafiltration of Ig is known in the art (e.g. Figure 2), and Van Holten teaches nanofiltration of isolated fraction of Ig results in substantially pure, virus free Ig formulations.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

NO CLAIMS ARE ALLOWED.

The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.
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